

Section 3, Remarks:

Re-examination and reconsideration of this case is respectfully requested in view of the foregoing amendments to the claims, the Declaration of Dr. Novotny submitted herewith and these Remarks.

15 claims are in this case. Applicant's traverse of the Restriction and Election of Species requirements is of record. The claims do not stand or fall together.

Amendments to Claims; No New Matter Added; and Response to the 112 Rejections:

In this section of the Response, Applicant treats both the support for the amendments and the three 112 rejections. The latter have been rendered moot and should be withdrawn.

Claims 1 and 10 have been amended to resolve the three instances of alleged indefiniteness under 112 and the refusal of the Patent Office to treat the preamble language as a limitation, in spite of the case law cited in the response to the Final Rejection in the parent case. These issues were set forth on pages 5 – 9 and 11 of the Detailed Action. In addition the amendments to the claims place them in better condition for appeal. Entry of the amendments is requested.

In respect to the refusal of the Examiner to give weight to the preamble language (page 11), note that **the preamble language was the necessary antecedent basis for reference in the sub-parts of main claims 1 and 10 to the limitations: “said person in need of treatment”, “said tissues” and “said adverse periodontal conditions”**. Accordingly, the ignored parts of the preamble in fact were present in the body of both main claims, and the refusal to give them weight proves Applicant's point that the Examiner is improperly parsing the claims. Ignoring claim limitations does not make rejections proper or sound.

However, in an attempt to move forward with the prosecution by rendering this point moot, the amendments to part a) of main claim 1, and part b) i) of main claim 10 have been imported from the preamble. Since the language was in the claim previously, and was not objected to or rejected, that language is therefore supported. Note that the present amendatory language is supported throughout the text of the Specification in places too numerous to be worth burdening the record here or causing Applicant unnecessary further expense by citation.

The “any’ dosage” 112 rejection (1st 112 rejection on pages 5 – 7) has been rendered moot by insertion of the aliquot amounts “;75 – 3 ml” per unit in part b) of main claim 1 and part b) ii) of main claim 10. **The effectiveness of such low dosages is probative of unexpected results, a significant indicia of patentability.**

The second 112 rejection of “releasably absorbed” (pages 7 and 8) is both curious and wrong. On the one hand the Examiner supposes a significant level of ignorance of the “skilled

artisan” by that rejection. Then in the 103 rejections, the “skilled artisan” is all knowing and ingenious. Apparently the Patent Office can play fast and loose with how smart the “skilled artisan” is to suit its purposes. That is improper.

Accordingly, Applicant accepts the Examiner’s finding that the skilled artisan would not clearly comprehend the language “releasably absorbing”. That is now the standard of the level of skill in this art to apply to this case.

To move forward, Applicant has amended the claims by deleting “absorbing” and replacing that word with – retained --. Please note the Specification discloses the claimed delivery units as having the property of “absorbing and releasably retaining treatment solution” on page 8, lines 6 and 7. Accordingly, the deletion of “absorbed” and insertion of -- retained -- is supported, and renders the rejection moot. Note that the buccinator muscle squeezes out the medicated fluid to lave the diseased tissues. The Specification refers to the fluid as expressed from the rolls. That is the concept of releasing the fluid contained (absorbed) by the rolls.

The third 112 rejection, that a narrow included range in a broader recitation as being improper (Detailed Action, pages 8 and 9), the claim language “life activities, including” has been changed to -- life activities of speaking and moving around --. This is supported, *inter alia*, throughout the Specification, including at page 2, line 30.

Accordingly, all three 112 rejections are now moot and should be withdrawn.

The remaining amendments are minor grammatical changes to make the claims more readable.

It is clear that no new matter has been added, the amendatory language being extensively supported throughout the Specification, the Original Claims as filed and the Drawings.

Response to the Seven Different §103 Rejections of Claims 1-4 and 6-15 over 6 References:

Somehow Applicant has gotten off on the wrong foot with the Office. Applicant regrets that and apologizes for whatever set the Office on edge. Applicant requests the Examiner to please take a breath, clear her mind of a preconception of non-patentability and recognize that however simple the solution of this invention seems to be, this invention, this discovery, this combination, is deserving of patent protection. This is not a submarine application; no big consumer products companies will be hurt. The Commissioner tasks Examiners to assist inventors (recall the Commissioner’s Guidelines, pg 17 below). This invention is a delivery system to effectively target and treat periodontal conditions through a small aliquot of anti-microbial carried in a comfortable, buccal vestibule-sized cotton roll that does not disintegrate by action of the buccinator muscle, for extended-time, targeted delivery at the site of the infection. In fact it

works, unexpectedly well, and was never suggested or taught by the “skilled artisans” of the prior art.

The Examiner is respectfully asked to stop using hind-sight. Surely she has experienced bad breath from time to time. What is her solution? Mouthwash, undoubtedly. But she, who claims to either be, or know what one of ordinary skill in the art would think, did not think of cotton rolls as a delivery platform, and, as clearly stated in the Novotny Declaration, the art does not teach or suggest the inventive system claimed to one of ordinary skill in the art. He has far more experience than the Examiner in this field; his conclusion should be respected and found conclusive.

It is Applicant’s position that the Declaration of Dr. Novotny clearly rebuts the PTO argument in each of the seven rejections under 103 that there is a *prima facie* case of obviousness. The multiplicity of rejections is an unnecessary “piling on” and 21 pages of Detailed Action verbage does not make the rejections any more sound.

Dr. Novotny is better able than the PTO to determine the level of ordinary skill in the art. Indeed, the Office Action fails to identify who is one of ordinary skill in the art, and what is their level of experience. Indeed, the Office Action repeatedly refers to “the skilled artisan”. The statute does not refer to “the skilled artisan”. It is clear in the 103 rejections that the Examiner considers the mythical, undefined, unidentified “skilled artisan” to be a lot more percipient and inventive than “one of ordinary skill in the art”. But that is not the law.

However, the Examiner in the 112 rejection opines that same “skilled artisan” does not understand that an absorbent material can release the fluid it absorbed. We now have an issue of law, whether there are two different standards of level of skill in the art: one for a 112 rejection and a different one for a 103 rejection. It is Applicant’s view that the two standards in the Office Action are entirely inconsistent, and shows the hindsight nature of the rejection.

The reliance of the Examiner on a “skilled artisan” is simply code for saying “one of extra-ordinary skill in the art”. That is not in the statute. That is not the law. There is no test in the statute permitting what a “skilled artisan”, one of extra-ordinary skill in the art would find obvious. The Examiner may be one far above ordinary skill in the art, and it is understandable, but not excusable, that the Examiner may find it difficult to perceive and apply the appropriate level of ordinary skill in the art.

Dr. Novotny’s Declaration also puts the finger on a key issue here. He shows clearly that one of ordinary skill in the art would not find it obvious to pick out of the references the isolated elements that the Examiner has selected. The Examiner has provided no basis for showing why only one specific alternative in Masci, trying a “dry composition” (Col 8, line 8)

“applied to articles such as dental aids and the like including cotton rolls” (Col 8, lines 13 – 15) for an unstated, and therefore unknown treatment, would be picked out of Masci. Even so, that’s not the invention

Dr. Novotny points out that to one of ordinary skill in the art, Masci would be merely a disclosure of binary mixtures of dequalinium and cetyl pyridinium salts as an anti-microbial. One of ordinary skill in the art would focus on the Masci, teaching that: “The majority of the antiseptic compositions incorporating the active ingredients of the invention will, however, be aqueous solutions. Such solutions may contain substantial amounts of other materials such as alcohol, glycerine and the like or any other substances which does not destroy the antimicrobial activity of the compositions.” (Col 8, lines 20 – 26). The use of aqueous solutions by themselves is the dominant teaching; and that is a distinctly different alternative than dry powder.

Keep in mind that one of ordinary skill in the art knows that cotton rolls used by dentists are used dry to absorb saliva. The art cited by the Examiner confirms that. Masci does not say to wet the cotton rolls. The only way the Examiner can assert that opinion is merely as such, an unsupported opinion based on hindsight view of Applicant’s own specification. Masci does not say to wet rolls. One of ordinary skill in the art would not read that into Masci by itself, or in view of the other references, as clearly shown by the Novotny declaration.

In any event, the Examiner’s unsupported opinion as basis for a 103 rejection is not the law. Consider what the law really is: The Board of Patent Appeals and Interferences does not condone that approach, stating in Ex parte Stern, 13 USPQ 2d 1379 at 1381:

“The examiner should be aware that “deeming” does not discharge him [or her] from the burden of providing the requisite factual basis and establishing the requisite motivation to support a conclusion of obviousness. [Citing cases] The examiner’s reference to unidentified phantom prior art techniques falls far short of the mark. [Citing cases] Accordingly, the examiner’s rejection of the appealed claims under 35 USC 103 as unpatentable over any of the primary references, considered singly, is reversed.”

Misreadings of the references based on an Examiner’s opinion of what they state or what a “skilled artisan” might read into them are not support for the rejections. The Examiner merely stating his/her opinion of what is obvious does not discharge the Examiner’s burden of presenting factual evidence. And parsing the reference in view of the Applicant’s Specification is not factual evidence. The Examiner is also invited to cite a case that states that an Examiner’s unsupported opinion is a proper basis for the Office asserting it has made a *prima facie* case.

One of ordinary skill in the art would find Masci to be merely of an historic interest, possibly the inventor of cetyl pyridinium salts as antimicrobials, in view of their overwhelming familiarity today with CPC salts as ubiquitous antimicrobials. The Examiner cites no clear

direction in Masci to use a binary mixture to wet a cotton roll of a defined size and aliquot content as a targeted delivery system for treatment of bad breath and gingivitis. Nor does Vermeer give better direction. It does not cure the defect in Masci.

Rather, the only reason the Examiner focuses on the cotton rolls, ignores the dry powder and tries to apply the aqueous solutions to the cotton rolls, is because of the teaching in Applicant's Specification. The Examiner has not rebutted the case law, nor can she because the PTO is not the Court, that it is improper to use Applicant's Specification as the source of the teaching to pick isolated elements from the prior art and to re-assemble them in ways not suggested by the prior art into the claimed invention.

Indeed, the Novotny Declaration shows that the other references, Wiesel, Julius, Speaker and Copelan, applied against the claims clearly push one of ordinary skill in the art to the direction of dry rolls, dry sponges, dry pads on handles, dry wedges on handles, and plastic strips to apply to teeth. That is, with all the art arrayed in front of one of ordinary skill in the art, Dr. Novotny's Declaration clearly shows that one of ordinary skill in the art would not pick out an aqueous solution of Masci and wet cotton rolls to solve bad breath problems. **That is particularly the case since one of ordinary skill in the art only uses cotton rolls in the dry condition as absorbers to keep the field of dental work dry, replacing them with fresh dry rolls as soon as they get saturated with saliva or rinse water.**

As set forth in the prior responses, the test of the law is not "obvious to try". The requirement for motivation is the other side of the obviousness coin. Would one of ordinary skill in the art, not extraordinary skill in the art, not a skilled artisan, find it obvious to pick defined elements out of references and combine them in a particular way to produce the invention, without resort to experimentation. As Dr. Novotny clearly states, one of ordinary skill in the art would not do that. The art cited by itself does not do that. And the Examiner is singularly not in a position to really know the level of ordinary skill in this art. Dr. Novotny is.

The secondary references of Wiesel, Julius, Speaker and Copelan do not cure the defects in Masci and Vermeer that the Examiner admits in the Detailed Action. The Declaration of Dr. Novotny dissects these references in detail, and concludes that the invention is not obvious. All seven of the 103 rejections are unsound and should be withdrawn.

Vermeer is directed to an alkyl aldonamide compound-containing composition. It does not cure the defects of Masci. Nowhere does it suggest a particular delivery platform for targeted treatment in combination with CPC of Masci. Applicant's invention is not directed to tooth paste or mouthwash. At best Vermeer suggests use in a mouthwash, which might include the "aqueous solution" of Masci (Col 8, lines 20 – 26), but Applicant's invention is not a mouthwash. Again,

the Office fails to address the delivery platform nature of the inventive combination.

Wiesel is directed to white strips. It contains no teaching of buccal vestibular use, shape, functionality or aliquot size. This is another tooth care reference. What it teaches in combination with Masci is not clear. One of ordinary skill in the art would have to experiment to see whether the peroxide compounds in Wiesel would not degrade the CPC and aldonamide compounds of Masci and Vermeer. Wiesel does not direct one of ordinary skill in the art to pick the cotton rolls out of Masci, wet them, size them for the buccal vestibule, and use them for bad breath and gingivitis treatment, particularly in view of the overwhelming dry use of cotton rolls in dental procedures with which one of ordinary skill in the art is familiar and uses on a daily basis. The combination of the 3 references does not render the claimed invention obvious; see the Novotny Declaration.

Julius shows a dry dental sponge. But that is not the invention.

Speaker is directed to a delivery system for topical applications comprising, not a cotton roll, but a highly viscous carrier containing dissolved or dispersed topically-active agents that are microencapsulated for sustained release. He mentions in passing **“very elaborate and somewhat uncomfortable methods of treatment”** of gingivitis, namely **“implanting in the periodontal sulcus one or more coils of an antibiotic-impregnated cotton or nylon braided cord”**. Clearly a roll is not a cord, and the claimed rolls are not “coils of braided cord”. More importantly, the inventive delivery platform rolls are inserted in the buccal vestibules, not IMPLANTED surgically in the periodontal sulcus. It should be noted that the treatment referred-to in Speaker is a surgical procedure directed to periodontitis, not gingivitis. The reference to “periodontal sulcus” indicates a pathologic condition, a 3 – 5 mm deep detachment of the tissue from the teeth and jawbone accompanied by bone loss, and not something effectively treated by mouthwash.

Coplan is directed to a dry, combination teeth and tongue brush, in a pad or wedge form that can also include a loop of dental floss. The package is not vapour impervious, and all the teaching is to a dry product. Again this reference is directed to teeth and tongue, not the application-specific combination claimed. Clearly Coplan is not resealable, and not pocket sized. Its relevance is not clear.

The rejections repeatedly refers to one teaching or another, always of course one that is missing from the references, as being “prima facie obvious to the “skilled artisan” (indeed, in conjunction with every rejection). The rejection also take the position that the use of any packaging would have been obvious to the “skilled artisan”. The only packaging shown is the very different, non-water proof packaging of Coplan, which is for a dry product.

In addition, the rejection takes the position that express motivation is not required, citing the MPEP. Sorry, the MPEP is not the law. *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984), held that *the prior art itself must suggest the combination of references*. That's the law, not the MPEP, which does not even cite *In re Gordon*, because it is a biased position paper of the Office.

Even more amazingly, the Office Action states on page 19 that "The motivation to combine the references is legitimate and is clearly supported by the fact that improved results would have motivated the skilled artisan [sic: there we go again, the unknown, non-statutory "skilled artisan"] to combine the references to enhance the therapeutic benefit or effect."

We now have another issue of law. The PTO is taking the position that all motivation in a medical device case, or chemical case, or perhaps all cases, is not necessary because of the desire of any art to have improved results. That is not the law. Indeed, this is a direct frontal assault on the law of improved results, because that position of the Office in effect says "If you show improved results, that proves the motivation." The law is that improved results are strong indicia of patentability, not the right to combine disparate elements out of the prior art, selected by an Examiner's hindsight use of the Applicant's Specification as a parts list and blue print.

Existence of a part is not motivation for a combination; the Examiner is requested to cite a CAFC case that says it is (not *ex cathedra* MPEP language, or the Examiner's "deeming" something obvious). Further, existence of improved results does not supply the motivation to assemble a combination, and only one combination, out of the parts.

The flaw in the Examiner's thinking is that one of ordinary skill in the art would not have known or expected the improved results in advance. Only by reading the Applicant's Specification would the Examiner have known about the improved results. Not knowing the improved results in advance, one of ordinary skill in the art would not even attempt the combination of references in the hindsight manner suggested by the Examiner.

One of ordinary skill in the art does not see in the references any that flexure of the buccinator muscle, e.g., during speaking, acting on and as a result of the presence of the cotton rolls open the sulci so that the antibacterial treatment fluid can target those hidden reservoirs of the bacteria contributing to bad breath.

There is so much wrong with the above-referenced thinking in the Office Action that it is hard to know where to begin. Let's start with the principles of law applying to obviousness rejections. In essence the rejections are trying to state the claims are obvious in the absence of prior art; whatever factual gaps there are in the reference are filled in by an unsupported assertion that the missing information is *prima facie* obvious (without a shred of support), or is

supplied by the Examiner's omniscient knowledge of what is obvious to a non-statutory "skilled artisan" that need not, and indeed can not and will not, be articulated. *Fortunately, that is not the law.*

That the Examiner can not just deem something obvious, or *prima facie* obvious, without support has been discussed (*Ex parte Stern*, above on page 12). And as to combinations of references, the fundamental principle, as articulated by the Court of Appeals for the Federal Circuit in *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984), is that the prior art itself must suggest the combination of references. In *Gordon*, the Court rejected the idea that the prior art devices could be modified to produce the claimed device as a proper basis for an obviousness rejection, holding the combination is not proper unless the prior art actually suggests the desirability of such a modification.

In *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 8 USPQ2d 1468 (Fed. Cir. 1988), the Court held that to pick and chose elements from references to recreate the invention is not proper. And in *Northern Telecom, Inc. v. Datapoint Corp.*, 15 USPQ2d 1531 (Fed. Cir. 1990), *cert. denied*, 498 U.S. 920 (1990), the Court held that

"[i]t is insufficient that the prior art disclosed the components of the patented device, either separately or used in other combinations; there must be some teaching, suggestion, or incentive to make the combination made by the inventor." (Emphasis added).

These governing principles were applied by the Court in holding in error the obviousness rejections in *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990) and *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990), among many cases. *In re Mills* specifically held that although the prior art device could be modified to run the way the applicant's device was claimed to run, "there must be a suggestion or motivation in the reference to do so." 16 USPQ2d 1430. Since there was none, the rejection was in error and was reversed. More recently, in *Sensonics, Inc. v. Aero-sonic Corp.*, 38 USPQ2d 1551 (Fed. Cir. 1996), the Court reiterated this principle, holding there was no teaching or suggestion in the prior art that would have led a person skilled in the art to select the specific structures and concepts and combine them in the manner of the invention of that case.

As a further principle, both the Courts and the Board of Appeal have long held that the suggestion for the combination in the references cannot come from the Applicant's Specification, see, for example, *Ex parte Brack*, 134 USPQ 445 (POBA 1961). The reason is simple: Applicant's Specification is not prior art. *Applicant's specification cannot be used as a parts list to search for disparate parts in the art, and then used as a blueprint to assemble the selected parts*. The sources for the motive not only to select the parts, but also the direction for

reassembling them into the claimed combination to obtain the desired result, must come from the references.

The above principles were not followed in this Office Action. “Prima facie obvious” without support, is not the law. Nor are “improved results” the legal source for motivation to combine references.

What is most pernicious here is that the rejection has used Applicant’s Specification to provide the motivation, then says, with disrespect, that the claims “would have been plainly obvious”. Again, since Applicant’s specification is not prior art, it cannot be used as either a parts list or a blueprint for the combination.

Finally,

“Office personnel should indicate how rejections may be overcome and how problems may be resolved. A failure to follow this approach can lead to unnecessary delays in the prosecution of the application.”

Further:

“... every limitation in the claim must be considered. Office personnel may not dissect a claimed invention into discrete elements and then evaluate the elements in isolation. Instead, the claim as a whole must be considered. See, e.g., Diamond v Diehr, 450 US at 188 –189, 209 USPQ at 9 (quoting from the case).”

Gosh, where are those quotes from? (From the Commissioner’s Guidelines. MPEP 2106.)

The result is that the seven 103 rejections based on 6 references in combination are unsound and should be withdrawn. The Novotny Declaration fully rebuts the unsupported and contrary to the teaching of the references “*prima facie*” case of the Office.

CONCLUSION

Entry and consideration of the amendments is respectfully requested. The seven 103 rejections over the cited should be withdrawn. The claims are not indefinite. It is Applicant’s view that claims 14 and 6 – 15 are now in condition for allowance and favourable action is urged.

An Interview to discuss the amended claims and the rejections over the references in view of the Novotny Declaration is respectfully requested.

Attachment: Declaration of Dr. Milo Novotny, 12 pgs

Respectfully submitted,
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End of Section 4.

End of Response to October 25, 2006 Office Action.